When considering an ADHD medication

Think Focalin XR first for a fast start

TWO CLINICAL STUDIES EVALUATED THE EFFICACY AND SAFETY OF FOCALIN XR® COMPARED WITH CONCERTA® (methylphenidate) IN A LABORATORY CLASSROOM SETTING

CLINICAL HIGHLIGHTS FROM:

STUDY 1: Efficacy and Safety of Extended-Release Dexmethylphenidate Compared With *d,l*-Methylphenidate and Placebo in the Treatment of Children With Attention-Deficit/Hyperactivity Disorder: A 12-Hour Laboratory Classroom Study

Muniz R, Brams M, Mao A, McCague K, Pestreich L, Silva R. *J Child Adolesc Psychopharmacol.* 2008;18(3):248-256.

STUDY 2: Treatment of Children With Attention-Deficit/Hyperactivity Disorder: Results of a Randomized, Multicenter, Double-Blind, Crossover Study of Extended-Release Dexmethylphenidate and *d,l*-Methylphenidate and Placebo in a Laboratory Classroom Setting

Silva R, Muniz R, McCague K, Childress A, Brams M, Mao A. *Psychopharmacol Bull.* 2008;41(1):19-33.

Primary efficacy end point in both studies: change from predose in SKAMP-combined score between Focalin XR 20 mg and Concerta 36 mg at 2 hours postdose.[1,2]

FOCALIN XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 6 years and older. FOCALIN XR is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Appropriate educational placement is essential and psychosocial intervention is often helpful. The effectiveness of FOCALIN XR for long-term use, ie, more than 7 weeks, has not been systematically evaluated in controlled trials.

Important Safety Information

WARNING: DRUG DEPENDENCE

FOCALIN XR should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence, with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Please see back cover for additional Important Safety Information.

Please see accompanying full Prescribing Information, including ***Boxed WARNING*** *and Medication Guide.*

ONCE-DAILY Focalin XR® dexmethylphenidate HCl Extended-Release Capsules 5, 10, 15, 20, 30 mg

First line. Fast start. Full day.

Two well-controlled studies confirmed the efficacy of Focalin XR versus Concerta at 2 hours postdose

Study Objective (for both studies)

- To compare the efficacy and safety of Focalin XR® 20 and 30 mg/day versus Concerta 36 and 54 mg/day in children aged 6 to 12 years with ADHD[1,2]

Study Design (for both studies)

- Randomized, double-blind, multicenter, crossover studies conducted in a laboratory classroom[1,2]
- Enrolled patients aged 6 to 12 years with ADHD (N=84 for Study 1, N=82 for Study 2) were stabilized on a total daily dose or the nearest equivalent dose of 40 to 60 mg/day of *d,l*-MPH or 20 to 30 mg/day of *d*-MPH for at least 2 weeks prior to screening visit[1,2]
- Five-period crossover design with a 6-day washout prior to randomization, allowing patients to serve as their own controls[1,2]
- Patients received 6 days of each treatment at home and the final dose in the laboratory classroom after they completed the predose classroom ratings[1,2]
- SKAMP* evaluations were performed at specified intervals postdose during the laboratory classroom visits[1,2]
- The primary efficacy end point was the change from predose in SKAMP-combined score of Focalin XR 20 mg vs Concerta 36 mg at 2 hours postdose in a 12-hour laboratory classroom setting[1,2]
- Patients were required to complete 7 visits[1,2]
  - One screening visit
  - One practice day (in classroom setting)
  - Five assessment days

Screening	Practice Day	Period 1	Period 2	Period 3	Period 4	Period 5 Final Visit
-21 to -2	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35
Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7

- In Study 1, mean baseline values were 20.3 for Focalin XR 20 mg and 20.7 for Concerta 36 mg[3]
- In Study 2, mean baseline values were 23.2 for Focalin XR 20 mg and 23.5 for Concerta 36 mg[4]

*The SKAMP (Swanson, Kotkin, Agler, M-Flynn & Pelham) rating scale measures change in attention and behavior from baseline.

Important Safety Information

FOCALIN XR is contraindicated in patients with marked anxiety, tension, and agitation, since the drug may aggravate these symptoms. Patients with glaucoma; motor tics; a family history or diagnosis of Tourette's syndrome; or a known hypersensitivity to methylphenidate or its components should not take FOCALIN XR. Patients should not take monoamine oxidase inhibitors during or within a minimum of 14 days following discontinuation of treatment, as hypertensive crisis may occur.

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and myocardial infarction (MI) have been reported in adults taking stimulant medication. Adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. All patients should be assessed for pre-existing cardiac conditions before starting FOCALIN XR, and it should be used with caution in patients with pre-existing hypertension, heart failure, MI, or ventricular arrhythmia.

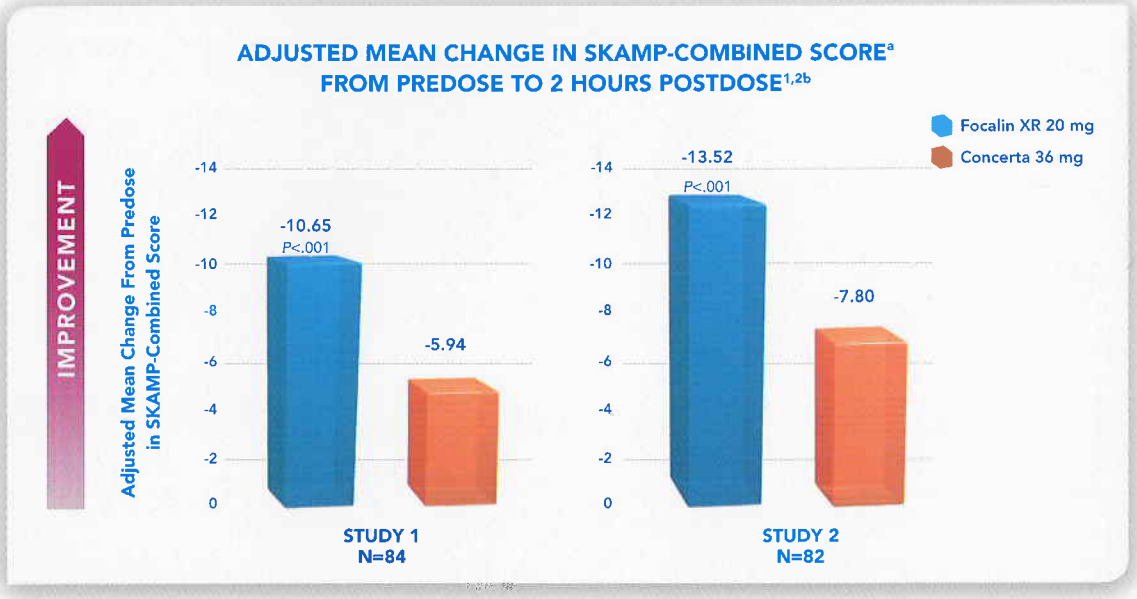
Primary End Point (for both studies)

SKAMP-Combined Score:

- Change from predose in SKAMP-combined score of Focalin XR 20 mg vs Concerta 36 mg at 2 hours postdose in a 12-hour laboratory classroom setting[1,2]

Primary Efficacy Results

Results from 2 placebo-controlled studies of children aged 6 to 12 years



[a]SKAMP-combined score was the primary efficacy outcome measure.

[b]For patients currently using MPH, the recommended starting dose of Focalin XR is half the total daily dose of racemic MPH. Patients currently using *d*-MPH immediate-release tablets may be switched to the same daily dose of Focalin XR.[5]

- Focalin XR demonstrated statistically significant superior efficacy versus Concerta 2 hours postdose[1,2]

Conclusion

- Two well-controlled studies confirmed the superior efficacy of Focalin XR 20 mg versus Concerta 36 mg at 2 hours postdose[1,2]

Important Safety Information

The most common adverse events (at least 5% and twice the incidence of placebo-treated patients) were dyspepsia (8%, 4%), decreased appetite (30%, 9%), headache (25%, 11%), and anxiety (6%, 0%) for pediatric patients on FOCALIN XR or placebo, respectively; and dry mouth (7%, 20%, 20%, 4%), dyspepsia (5%, 9%, 9%, 2%), headache (26%, 30%, 39%, 19%), and anxiety (5%, 11%, 11%, 2%) for adult patients on FOCALIN XR 20 mg, 30 mg, 40 mg, or placebo, respectively.

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Psychotic symptoms may be exacerbated in patients with psychotic disorders. Use with caution in patients with comorbid bipolar disorder. Treatment-emergent new psychotic or manic symptoms may occur without a prior history. Monitor for appearance or worsening of aggressive behavior or hostility.

Long-term suppression of growth has been reported with long-term use of stimulants. Growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

The threshold for seizures may be lowered. Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. FOCALIN XR should not be used in children under 6 years of age, since safety and efficacy in this age group have not been established. Periodic monitoring of CBC with differential is advised during prolonged therapy.

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References: 1. Muniz R, Brams M, Mao A, McCague K, Pestreich L, Silva R. Efficacy and safety of extended-release dexmethylphenidate compared with *d,l*-methylphenidate and placebo in the treatment of children with attention-deficit/hyperactivity disorder: a 12-hour laboratory classroom study. *J Child Adolesc Psychopharmacol.* 2008;18(3):248-256. **2.** Silva R, Muniz R, McCague K, Childress A, Brams M, Mao A. Treatment of children with attention-deficit/hyperactivity disorder: results of a randomized, multicenter, double-blind, crossover study of extended-release dexmethylphenidate and *d,l*-methylphenidate and placebo in a laboratory classroom setting. *Psychopharmacol Bull.* 2008;41(1):19-33. **3.** Data on file. Study CRIT124EUS12. Novartis Pharmaceuticals Corporation, East Hanover, NJ. **4.** Data on file. Study CRIT124EUS13. Novartis Pharmaceuticals Corporation, East Hanover, NJ. **5.** Focalin XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2010.

For more information, visit www.FocalinXR.com.

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